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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/324,343	06/02/1999	JOHAN H. GEERKE	ALZA-0022 ARC-2865-R3	1409

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/324,343	GEERKE ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 32-38* is/are pending in the application.

4a) Of the above claim(s) *1-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-20,32- 33, 35-36, 38* is/are rejected.

7)☒ Claim(s) *34 and 37* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 6, 2005 has been entered.

Claims 1-20, 32-38 are pending. On the April 24, 2000 submission, Applicant elected Group III, claims 18-31, for the prosecution. Claims 1-17 stand withdrawn as they are directed to non-elected inventions. Claims 21-31 are canceled. Claims 18-20, 32-38 are under consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 18-20, 32-33, 35-36, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barclay et al US Patent 5,248,310 in view of Wong et al US Patent 5,785,994.

The instant claims are directed to three-layer tablets comprising a first and second layer that contains a drug and at least one colorant, and a third layer containing a second and different colorant. The dependent claim further adds a coating layer to said tablets and methylphenidate chloride as the active ingredient.

3. Barclay teaches osmotic tablets comprising separate drug polymer and polymer layers wherein each layer is distinguishable from each other by a different color. Barclay specifically teaches the use of colorant to allow appropriate color contrast between layers of his formulation (see abstract, col 20, lines 26-60; col 7, lines 59-col 8, line 34). Barclay shows that coloring agents are used in the art for determining the formulation orientation. (see col 17, lines 20-56). At col 17, lines 20-55, Barclay describes an osmotic tablet comprising a white color drug containing layer and a reddish brown hydrophilic polymer layer. Barclay teaches the non-drug polymer layer to contain a reddish-brown color (see col 17, lines 40-44). Barclay describes the use of ferric oxide colorant as the colorant of choice.

Barclay then compresses the drug and non-drug layer together and coats the resultant solid osmotic tablet with a translucent coating. (see col 17, lines 39-51). Barclay coats the tablet with a translucent coating and describes that the drug/beneficial

agent layer is detectable through such translucent coating (col 5, lines 42-51). Since color difference is easily detectable by naked eye, Barclay's tablet inherently possesses capability to be detected by a colorant detector. In fact, Barclay detects or observes the white drug-containing layer from the reddish-brown polymer- layer in the tablet. (see col 17, lines 52-54). After detecting which side of the tablet contains the drug layer (in another words, detecting the orientation of the tablet), Barclay chooses to drill a passage whole through the drug-containing layer for delivering the drug from the osmotic tablet. (see cool 17, lines 55-57). Therefore, Barclay teaches the use of colorant for purposes of detecting orientation of a two layered osmotic tablet.

Barclay also teaches suitable size or shape for his tablets to allow comfortable oral delivery. (see col 6, lines 20-24, figures 1-3). Such suitable shapes include capsule- shaped tablets as depicted in figure 1-3 of Barclay's Patent. Barclay also teaches the use of methylphenidate hydrochloride as a suitable drug in his formulation. (see col 11, lines 13-15). Barclay does not teach a three layer osmotic tablet.

Barclay only fails to explicitly teach a three-layered tablet. However, preparing a two or three layer osmotic tablet is well within the level of an ordinary skill in the art.

4. For example, Wong teaches a three layer osmotic tablet using the same drugs, same polymeric moieties and same drilling technique as Barclay. Wong teaches a three or more layered tablet that provides a varying pattern of drug release (see abstract, col 2, lines 4-20). Such pattern is achieved by drug concentrations in each layer of Wong's formulation. Wong teaches three-layered osmotic tablets containing a port (see abstract). At least one layer of Wong's tablets contains a dye such as ferric oxide. Wong

discloses tablet dosage forms comprising three layers wherein first layer is drug free and is a push layer which contains a colorant such as ferric oxide (see col 17 line 23; col 20, lines 20-25) and the third layer comprise a colorant (see figure 3, col 16 lines 58-67, col 18 lines 1-42). Thus, adding additional drug layers is well within the scope of Wong's teachings.

The tablet of Wong comprises an exit port (see col 17 line 56) meeting the limitation of claims 25, 30 (see col 15 lines 15-18). Wong et al disclose that their tablets are prepared by pressing the three layers to form a solid core (see col 19 lines 10-18). Wong also describes methylpheidate as a suitable drug in his formulation (col 10, line 21). Wong essentially teaches the same tablets as Barclay. Except that Wong is a three or more layered tablet that provides a varying pattern of drug release. (see abstract, col 2, lines 4-20). Such pattern is achieved by drug concentrations in each layer of Wong's formulation.

5. Barclay and Wong are within the same field of endeavor and therefore their teachings are combinable. Barclay employs aspirin, steroids, methylphenidate, etc... (see col 11, lines 1-65, examples 1, 3 and 5). Wong also employs the same drugs (see Wong at col 10-col 11, lines 7-8).

Barclay describes hydrophilic polymers and hydrogels as suitable polymeric units (see col 13, lines 23-67). Wong also teaches the same polymeric moieties (see Wong at col 12, lines 44-col 13, line, 65).

Barclay teaches osmagents such as magnesium sulfate etc...(see col 13, lines 4-20). Wong teaches the use of the same osmagents (see col 5, lines 33-50).

Barclay uses the ferric oxide as the colorant in the polymeric layer (see example 2). Wong also uses ferric oxide as a colorant in his polymeric layer (col 17, lines 18-26).

The only difference between Barclay and Wong is that Barclay teaches a two layer osmotic tablet, but Wong teaches a three layer osmotic tablet.

6. Nevertheless, it would have been obvious to one ordinary skilled in the art at the time of invention to employ Barclay's method of detecting different layers in the three layer osmotic dosage forms of Wong, by incorporating a coloring agent, as shown by Barclay, in any desired layer, because the ordinary skill in the art would have had a reasonable expectation of success to use different colorants to facilitate ease of detection of each formulation layer.

Allowable Subject Matter

7. Claims 34, 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

8. Applicant's arguments filed on June 06, 2005 have been fully considered but they are not persuasive.

Applicant argues that the Barclay patent teaches a two-layer tablet and the Wong patent teaches a three-layer tablet. Accordingly, Applicant concludes that there is no motivation to combine the cited patents to reach the instantly claimed invention as neither of the cited references teach a tablet that has a two drug-containing layer. (see Remarks at page 10-11).

As the initial matter, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, all elements of the claims have been described by the cited references. Examiner has further explained a motivation to modify the cited patents to reach the instant claims. Accordingly, the rejection is based on the combined teachings of the references. Therefore, mere failure of one of the references to meet all elements of the instant claims does not render the instant claims patentable.

Applicant argues states that there is no evidence demonstrating that modification of the Wong dosage form would have been one that those of ordinary skill would have been motivated to make. (see Remarks at page 10, 2nd para.). In response Examiner does not understand Applicant's assertion for a need to provide evidence demonstrating the modification of the Wong's dosage form. USPTO is simply not required to provide experimental data or evidence to show *prima facia* obviousness. Applicant is reminded that [F]or obviousness under §103, all that is required is a reasonable expectation of success. *In re Longi*, 759 F.2d 887, 897, 225 USPQ 645, 651-52 (Fed. Cir. 1985). Here, the combined teachings of the references set forth a reasonable expectation of success for the reasons set forth above. Thus, the rejection is proper and his hereby maintained.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SREENI PADMANABHAN
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